

Wednesday, February 25, 2009

Check out the SPL Working Group WIKI @:  
<http://spl-work-group.wikispaces.com>

**Meeting Minutes:**

Q&A discussion regarding the deprecation of the document type "HUMAN PRESCRIPTION DRUG LABEL WITH HIGHLIGHTS (45129-4)"

*Why is this happening?*

- The FDA is not using the LOINC code to specifically render a specific style/output. Once the FDA moved away from a stylesheet with boilerplate text (adverse events statement, initial year of approval), there was less need for a separate LOINC for labeling with Highlights (aka Indexing Data Elements).
- The FDA has deprecated a number of terms over the last five years; this is not an extraordinary occurrence.
- The current validation is done by checking for the <excerpt> tag, rather than the LOINC code = 45129-4.

*Open Question: Are vendors using (still using) the LOINC of 45129-4 to render a PLR file? If so, how are vaccine SPL documents rendered in the vendor's software?*

- Of vendors responding – 2 (of 2) vendors indicated this was not an issue

*Have the regulations been changed such that PLR format is required for all labels beginning June 1, 2009?*

- The regulations concerning labeling have not changed

*If we have been submitting any R4 labels with the LOINC code of 45129-4, should we replace that LOINC with the Human Prescription Drug Label LOINC [34391-3]?*

- If the file is going through the eListing process, the code should be changed so that the file would not fail validation.

Discussion regarding changes in sponsor processes due to SPLr4

**ACTION: Bring the latest results of the WIKI-hosted survey for discussion at next Process Communications Forum**

## Subteam Updates

### OTC Subteam

- The OTC group has been hosting vendor presentations. One vendor is doing an additional, follow-up presentation.
- Not a lot of discussion during the vendor presentations. On a 1-on-1 basis, people suggested that these have been helpful.
- Seeing the process over and over again helped reinforce the upcoming change in process
- Companies are still ‘popping up’ that have not heard of the changes. Mailing lists via DIA, RAPS, FDLI, 10-20 companies (API manufacturers), DUNS – can they isolate the categories that might be affected. Federal Government categorization

**ACTION: Create short press release that reminds/alerts about impending process team**

**ACTION: Bring discussion about LinkedIn back to Leadership Team**

**ACTION: Marcia to handle general outreach**

### Medical Devices Subteam

- HL7  
At last HL7 meeting, SPL was noted as a way to provide medical device information; Plans are to work with a small group of medical devices that currently have NDC codes
- We still don’t have a lot of hard data (deadlines, timelines)
- The group is fairly small. Anyone interested in joining/re-joining the Medical Device subteam, please contact Myron Finseth @ [myron.finseth@medtronic.com](mailto:myron.finseth@medtronic.com).
- Good idea to start developing a strategy on how to communicate and get the message out to the device industry.

### ER/DL Subteam

- Running into a lot of process questions, such as exports of products, use of labels in foreign languages, other issues relating to SPL for extra-US issues.  
Next week’s webinar from FDA is on Product Details – look for more information coming from discussions with the Drug Listing group
- Continuing to meet every two weeks, alternating with the dates of the Process Communication Forum

### Generic Subteam

- Currently meeting approximately monthly, on Tuesdays at 1 PM (Eastern)
  - Have had sessions with Q&A with FDA, D&B
  - DUNS numbers are a complicated issue for certain companies that have grown by acquisition, and may have multiple interactions with vendors, contract organizations
- ACTION: If you are interested in editing WIKI content (not just viewing), please contact Jeffery Karp at [jmkarp01@comcast.net](mailto:jmkarp01@comcast.net) or via the WIKI.**

### Biologics Subteam

- Currently meeting approximately monthly
- Letters coming from FDA (CBER) to sponsors containing UNII codes and how they were determined

## Veterinary Medicine Subteam

- Face-to-Face Session on February 17
- Setid no longer needs to match rootid
- New terminology for animal health (PAIL, Routes of Administration) – look for these to be added to the lists on the SPL Resources page in the near future.
- Encouragement to use standard LOINC codes whenever possible to provide additional value, easier to find issues like ‘Indications’

## AOB:

*Over 270 organizations are signed up for either an FDA webinar or Face-to-Face over the next couple months*

*FDA is working on an OTC template now, and expects to release this in the near future.*

*SPL survey - Look for a new set of results in a couple of weeks*

**Next Meeting scheduled for Wednesday, March 11, 2008 from 1 – 2:30.**

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